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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

September 30, 1999

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Program Priorities in the Center for Food Safety and Applied Nutrition
Docket No. 98N-0359

Dear Sir or Madam:

This comment is submitted in response to the Agency's notice in the *Federal Register* of September 1, 1999, calling for comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for the year 2000. This comment is submitted on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA) and is focused only on program priorities for CFSAN relating to the regulation of cosmetics.

CTFA is the national trade association that has represented the cosmetic industry since 1894. Its almost 600 active and associate members have annual sales ranging from less than $500,000 to more than $3 billion. Together, CTFA member companies market more than 90 percent of the $25 billion in cosmetic products sold annually in the United States.

Our position on Agency priorities for the coming year is substantially the same as in 1999. Most important, full CFSAN funding for cosmetic regulation was restored last year and it currently appears that funding will be continued for FY 2000. CTFA believes that this funding should be used to focus on the maintenance of a credible cosmetic regulatory program. This program should take advantage of the substantial efficiencies created by CTFA's self-regulatory programs - the Cosmetic Ingredient Review, Voluntary Reporting Program, International Cosmetic Ingredient Dictionary, CTFA Technical Guidelines, Cosmetic Industry on Call and others - that provide the public and FDA with extraordinary assurance of the safety of cosmetics and allow the Agency to focus its resources on the most critical issues.

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We believe the Agency's specific priorities for cosmetics in 2000 should be the following:

1. International Harmonization: Maintain full Agency participation in efforts to obtain international harmonization of cosmetic regulations, including the Trans Atlantic Business Dialogue and other harmonization efforts at all levels of government.

2. CFSAN Participation in Voluntary Industry Programs: Maintain full Agency participation in the Cosmetic Ingredient Review (CIR) and other voluntary industry programs.

3. Voluntary Reporting Program: Continue efforts to restore Parts I and II of the Cosmetic Voluntary Reporting Program through development of an efficient and easy-to-use, internet-based reporting system. Resources should also be provided to publish the database obtained from 20 years of adverse experience reporting under the discontinued Part III of the Cosmetic Voluntary Reporting Program.

4. Color Additive Approval: Move as rapidly as possible to complete the approval process for the pending Color Additive Petition for Carbon Black.

International Harmonization

International Harmonization remains one of the most important priorities for both industry and government. The smooth flow of goods across national borders is essential to the ability of all companies, large and small, to compete in a global marketplace. Full access to the international marketplace for companies and consumers should not be arbitrarily restricted by differences in regulatory approval or labeling requirements.

We believe it is incumbent on FDA to take a leadership role in working with government officials in all the major world markets to eliminate these barriers to international trade and to standardize, to the fullest extent possible, the requirements for marketing and labeling cosmetic products.

In 1999, FDA has made significant efforts to participate in international meetings designed to facilitate international harmonization of regulations. We urge the Agency to increase those efforts in the coming year.

CFSAN Participation in Voluntary Programs

The CIR Expert panel has made a number of changes in CIR procedures during the past year that were intended to improve public participation in the process and to further strengthen the credibility of the program. These changes involved establishment of a rotation schedule for Expert Panel members and the opening of Expert Panel "team meetings" to the public. We hope that these changes will result in the continued participation of FDA in all aspects of the CIR process.

CIR is the cornerstone of the industry self-regulatory process. We believe that this program, established in 1976, was ahead of its time in using industry resources to ensure the safety of cosmetic ingredients. The cosmetic industry spends in excess of $1 million to fund the activities of CIR so that the safety of cosmetic ingredients can be evaluated by the CIR Expert Panel, members of which must meet the same conflict of interest standards as outside experts on FDA panels. The full participation of FDA through the presence of appropriate CFSAN officials at CIR Expert Panel meetings is essential to the continued success of this program and the savings that it provides to limited CFSAN resources.

Similarly, we look forward to continued FDA participation in other industry self-regulatory programs such as the Cosmetic Voluntary Reporting Program and to the effort to develop and maintain international nomenclature for cosmetic ingredients listed in the *International Cosmetic Ingredient Dictionary*.

Voluntary Reporting Program

CTFA supports the Agency's efforts to restore Part I (establishment registration) and Part II (ingredient usage reporting) of the Cosmetic Voluntary Reporting Program. These programs were terminated during the time that CFSAN funds for cosmetic regulation were cut. We were pleased to be able to support the restoration of those funds and believe the restoration of Parts I and II of the Voluntary Reporting Program is an appropriate activity. CIR uses these data in determining its priorities for ingredients to be reviewed.

Because the program was interrupted, restoration of full participation will require both education of new personnel and efforts to find a less resource-intense method for supplying ingredient statement data to FDA. CTFA is currently working with the staff of the Office of Cosmetics and Colors to develop an internet-based system for providing information to FDA. This would greatly ease the burden of reporting on company staff,

and would also make it easier to keep the system up-to-date. We look forward to successfully completing that project in cooperation with FDA.

Another matter related to the Cosmetic Voluntary Reporting Program which we view to be very important is FDA's compilation of data from the discontinued Part III of the program - reports of adverse experience data. The Agency correctly determined that this part of the program was no longer justified because approximately 20 years worth of data had been collected. FDA stated that it would compile the existing data so that it could be used as a baseline against which each company could evaluate any current reports of adverse experiences. We believe that this project is important; and, if it is not completed in 1999, we urge CFSAN to supply the necessary resources and level of priority to complete the task in 2000.

Color Additive Approval

Initial efforts to gain listing of Carbon Black as a color additive for use in cosmetic products began in 1967. At more or less regular intervals up to 1974, FDA and CTFA (then known as the Toilet Goods Association) traded correspondence, with questions from FDA about the ingredient identified as Carbon Black, and responses from CTFA. In 1986, CTFA submitted a formal petition for the use of Carbon Black in cosmetic products. The petition was acknowledged as suitable for filing in December 1986.

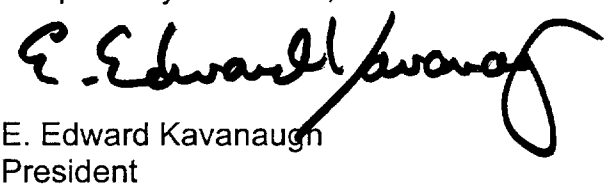
Since that time we have continued the question and answer approach begun in the 1960s. Unfortunately, this approach has led to addressing the problems in a piecemeal fashion that has extended the time spent on this petition inordinately. In a meeting on February 3, 1999, CTFA was led to believe that all questions regarding toxicity and potential hazard had been addressed satisfactorily, and that only analytical questions pertaining to identity and specification testing remained to be addressed. Questions from FDA were proposed in a letter on July 26, and those questions are being addressed by industry at the present time.

We have since learned that another round of toxicology review might be necessary, but that review will not commence until we have submitted the chemistry information and it has been evaluated. This would seem to be counterproductive, ensuring that it will take additional time to finalize this petition review. We would like to request specifically that FDA take the time to review this petition and identify all of the questions that are still outstanding. In this way we can hope to obtain final approval of this petition in the most efficient manner.

Conclusion

CTFA looks forward to again working with the Office of Cosmetics and Colors in CFSAN on these issues in 2000. We believe that the combination of industry self-regulation and FDA enforcement authority for cosmetics is one of the strongest examples of efficient government-industry cooperation to ensure that the consumer has a broad selection of safe cosmetic products in the marketplace. The synergy between industry self-regulation and CFSAN enforcement powers saves the government a large amount of resources and leaves the Agency free to focus on those issues that really do need a much larger commitment of scarce government resources.

Respectfully submitted,



E. Edward Kavanaugh
President

cc: Joseph A. Levitt (HFS-001)
John E. Bailey, Jr., Ph.D. (HFS-100)